K00 3436

FEB - 2 2001

510(k) Summary

Surgi-Vision Guidewire Coil

Common/Classification Name: Accessory to
Magnetic Resonance Diagnostic Device, 21 CFR 892.1000

Surgi-Vision, Inc.
9250 Rumsey Road, Suite 100
Columbia, MD 21045

Contact: Nancy E. Taylor, Prepared: November 3, 2000

A. LEGALLY MARKETED PREDICATE DEVICES

The **Surgi-Vision Guidewire Coil** is substantially equivalent to the Surgi-Vision Stylet Coil, which was cleared for marketing on March 14, 2000, in premarket notifications K994436. In addition, the Lake Region Manufacturing ONTRAC-PC Guidewire, which is covered under existing 510(k) K901224 and K935170, is used for comparison due to it's similar construction and intravascular use.

B. DEVICE DESCRIPTION

The **Surgi-Vision Guidewire Coil** is a specialty coil for use in MRI imaging of the peripheral vasculature. The signals picked up by the coil are conducted through a small coaxial cable to a connection with the standard surface coil connector for GE 1.5T MRI systems. The coil and cable are completely sealed inside the insulating layer.

C. INTENDED USE

The Surgi-Vision Guidewire Coil is recommended for high-resolution Magnetic Resonance Imaging of the peripheral vasculature. The single use, disposable coil is designed for insertion into an artery or vein of a patient during MRI scans in order to obtain improved image quality in the peripheral vasculature. The flexible coil facilitates placement of the coil in the peripheral vascular anatomy similar to typical guidewires that are currently in use. The coil would most commonly be used through femoral artery access. The handling characteristics of this device are familiar to

vascular interventionalists.

D. SUBSTANTIAL EQUIVALENCE SUMMARY

The **Surgi-Vision Guidewire Coil** has similar but not identical indications for use as the legally marketed predicate device. However, the intended use, providing internal reception of MRI signals for the purpose of creating an MRI image of nearby anatomy, is the same.

The **Surgi-Vision Guidewire Coil** has similar technological characteristics to the predicate devices. Both proposed and predicate device (Surgi-Vision Stylet Coil) have an electronic matching circuit, a connecting coaxial cable, and an internal probe with a radiofrequency receiving coil. However, there are differences in construction and design that make it necessary to provide performance data to assure substantial equivalence. Such performance data are available and do demonstrate substantial equivalence.

E. TECHNOLOGICAL CHARACTERISTICS

See Section D, above.

F. TESTING

Surgi-Vision carried out testing and/or analysis of the **Surgi-Vision Guidewire Coil** that addressed the following issues:

(1) Possibility of excess RF heating;

(2) Possibility of increased susceptibility of patients to peripheral nerve stimulation;

(3) Imaging performance; and

(4) Mechanical testing.

The results of the heating experiments demonstrate that there is no excess heating when SVGC is positioned in a phantom that is representative of worst case clinical conditions. The change in temperature observed during use of the SVGC is not significantly different then that observed without the coil.

The calculations done to determine current leakage by the MRI pulsed gradient field demonstrate that there is no possibility of increased susceptibility of patients to nerve stimulation.

The imaging performance was evaluated in a canine model as shown in Exhibit VI. The canine model was selected for it's similarity of vascular structure and the ease of access. Comparison images were done using a body coil. The SVGC images demonstrated enhanced resolution of vascular regions compared to the body coil images taken with the same imaging parameters.

Mechanical test results demonstrated that there are no safety issues and that all of the performance specifications were met. Stiffness, tensile, tracking, torque, and electrical testing were all completed to the satisfaction of the specifications. Mechanical flexing resulted in insignificant changes in the electrical properties of the coils. These results are described in Exhibit XI.

G. CONCLUSIONS

This pre-market submission has demonstrated Substantial Equivalence as defined and understood in the Federal Food Drug and Cosmetic Act and various guidance documents issued by the Center for Devices and Radiological Health.

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 2 2001

Nancy E. Taylor
CEO/President
9250 Rumsey Road
Suite100
COLUMBIA MD 21045

Re: K003436
Surgi-Vison Guidewire Coil
Dated: November 3, 2000
Received: November 6, 2000
Regulatory Class: II
21 CFR §892.1000/Procode: 90 MOS

Dear Ms. Taylor:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

STATEMENT OF INDICATIONS FOR USE

510(K) Number (if known): K003436

Device name: Surgi-Vision Guidewire Coil

Indications for Use:

The Surgi-Vision Guidewire Coil is recommended for high-resolution Magnetic Resonance Imaging of the peripheral vasculature. The single use, disposable coil is designed for insertion into an artery or vein of a patient during MRI scans in order to obtain improved image quality in the peripheral vasculature. The flexible coil facilitates placement of the coil in the peripheral vascular anatomy similar to typical guidewires that are currently in use. The coil would most commonly be used through femoral artery access. The handling characteristics of this device are familiar to vascular interventionalists.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use √ OR Over-the-Counter Use _____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K003436